Department: **UAMS Institutional Review Board**
Policy Number: **15.3**
Section: **Consent**
Effective Date: **July 31, 2002**
Revision Dates: **February 8, 2005; June 24, 2004; October 11, 2002**

Subject: Waivers of Signed Informed Consent Documents and Waivers of Informed Consent Elements

Policy:

1. For research not subject to FDA regulations, the IRB may approve a waiver of some or all of the consent elements provided that the research fits into one of two scenarios.

1.1 Some or all elements of consent may be waived if:

1.1.1 The research involves no more than minimal risk to subjects;
1.1.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects;
1.1.3 The research could not practicably be carried out without the waiver or alteration; and
1.1.4 Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study.

1.2 Some or all elements of consent may be waived if the project is:

1.2.1 Conducted by or subject to the approval of state or local government officials;
1.2.2 Could not practicably be carried out without the waiver or alteration;
1.2.3 Designed to study, evaluate or examine one of the following four categories:

a) Public benefit of service programs;
b) Procedures for obtaining benefits or services under those programs;
c) Possible changes in or alternatives to those programs or procedures; or
d) Possible changes in methods or levels of payment for benefits or services under those programs.

2. For research subject to FDA regulations, consent may only be waived in certain life threatening situations. See Policies 15.2; 18.3 or 18.4 for more information.

3. For research not subject to the FDA regulations, the requirement for a written, signed informed consent from may only be waived if:

3.1 The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; OR

3.2 The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

4. For research subject to FDA regulations, except as allowed by the emergency use of a test article provisions, the requirement for a written, signed informed consent form may only be waived if:

4.1 The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

Procedure – Applicable to all expedited and full review studies.

1. Investigators must:

1.1 Submit a consent form or request and justify in the ARIA application why the study meets the requirements for either a waiver of written consent or a waiver/alteration of consent. The requirement for justification applies even in cases where the Investigator needs to use deception due to the possibility that subjects would behave differently if they knew they were being observed.

2. The IRB

2.1 Review the submission to see if it is subject to FDA regulations.

2.2 Review the waiver request, taking into account the importance of the research, the extent to which privacy will be invaded, the sensitivity of the information to which the investigators will have access, plans for further contact of the subjects, and the feasibility of obtaining consent from all subjects.

2.2.1 For studies requesting to use deception, decide whether the information to be withheld would influence the decision of prospective subjects about participating in the research. Research should not be permitted at all if the risk to subjects is more than minimal and the subjects are not being informed of things they would consider material to a decision to participate. Also decide if subjects should be debriefed either after participating in research unwittingly or after knowingly participating in research that involved some form of deception.

2.3 Decisions on informed consent, waivers of informed consent, documentation of informed consent, or requirements for debriefing will be described in the letter to the Investigator and reflected in the IRB minutes.